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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,849	02/12/2004	Samuel Chackalamannil	CV01148KB	5893
24265	7590	10/04/2005	EXAMINER	
SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT (K-6-1, 1990) 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033-0530			BERCH, MARK L	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/777,849	Applicant(s) CHACKALAMANNIL ET AL.	
	Examiner Mark L. Berch	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-12,22,23,27-30,34,35,37,39 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-12,22,23,27-30,34,35,37,39 and 41-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The examiner notes for the record that claim 44 is actually a new claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-12, 27-30, 34-35, 37, 39, 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The Y choice of $-(R^{23})(R^{24})N(H)-$ is clearly defective, as it provides for a N atom with 5 bonds, which is impossible. For whichever choice is made, applicants must show that one of ordinary skill in the art would have known that this choice, and not another, was intended. The traverse is unpersuasive. Applicants refers to an amendment, which is indeed supported by page 20, but new claim 43 has same text (see page 10, next to last line).
2. "Thioalkyl", which occurs in the definition of the substituents on page 6 and elsewhere, is not standard nomenclature. Thio as a generic prefix simply indicating the presence of sulfur. It could have a number of possible meanings. It is possible that the term refers to HS-alkyl-, which is properly called the mercaptoalkyl group. It is also possible that it is intended to refer to the alkyl-S- group, which is properly called the alkylthio group. It could possibly refer to the replacement of a carbon in an alkyl with a Sulfur, e.g. CH_3-S-CH_2- . Another alternative is that the sulfur could be a double bonded substituent (rather than a single bonded one as seen in mercaptoalkyl), e.g. $CH_3-C(=S)-CH_2-$,

properly called the thioxo alkyl. There might be some letters missing, so that what was intended was thiophenylalkyl, i.e. the alkyl is substituted by thiophene, or possibly thionoalkyl, i.e. alkyl substituted by $=C=S$. This specification gives no clear evidence as to which of these plausible choices was originally intended. The traverse is unpersuasive. First, even if applicants' reasoning were correct, and one could infer that what was really intended was mercaptoalkyl, the wording is still incorrect. As stated in *In re Zletz*, 13 USPQ2d 1320, 1322, "An essential purpose of patent examination is to fashion claims that are precise, clear, correct and unambiguous." This term is not correct. Second, the inference drawn is not supported. It is of course true that when a substituent appears on a stem, the substituent always appears at the left, and the stem at the right. That is the only way that substituents are ever correctly done. The fact that the specification has for example "hydroxyalkyl" simply reflects that applicants are using standard nomenclature. However, one cannot assume such a situation here because "thio" is, unlike "carboxy", not the name of a substituent. And even if one could, applicants have presented no reason for assuming that "thio" means a singly bonded sulfur, i.e. $HS-$, rather than a doubly bonded sulfur, i.e. $S=$.

3. What is the purpose of the structures on page 13? These are already covered by the first part of the definition, are they not? The traverse is unpersuasive. It is agreed that "or" provides alternative definitions for R50, etc, but these alternatives are already covered, so what is the purpose of this material? That is, the first part of the definition already provides for optionally substituted aryl. The first page 13 structure is in fact, an optionally substituted aryl, so what role does this play? Every page 13 structure is already completely covered by the page 12 text, so what is its role?

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4. The term “ester” (see e.g. R9, R10 in claim 27) is not a substituent, but a compound, e.g. ethyl acetate. As such, it has no valence and cannot be a substituent. The traverse is unpersuasive. Applicants point to the specification, but that simply confirms what the examiner has stated. The page 14 statement is as follows: “The term “ester,” as used herein, means compounds containing a substituted carboxylic acid (e.g., -COO-aryl).” (emphasis added). A compound cannot be a substituent.
5. The claim 27 formula is problematic. If the material in parenthesis is correct, then n and m can only be 2 (i.e. the material in parenthesis is -CH=CH-). Note that carbon must have 4 bonds. If e.g. m=3, then two carbons will be taken care of with -CH=CH- but the third will have only three bonds. Moreover, this conflicts with the requirement that the ring must be saturated, as is stated on page 12, line 7 of the specification. The traverse is unpersuasive. Applicants argue that R10 or R11 can provide the missing substituent. However, substituents by their definition, substitute, which means that they replace a H with themselves. Thus, they cannot provide something which is missing. Moreover, even if this were true, as noted, page 12, line 7 of the specification requires that the ring be saturated.
6. In the R10-R11 combined option (page 6, line 4), , the “optionally” is wrong. The ring must include at least one atom from the ring.
7. Further the “and/or heteroatoms” is not quite right. The “or” part is wrong. R10 and R11 cannot be both attached to just a heteroatom – no heteroatom has 2 hydrogens to replace. The traverse is unpersuasive. Yes, a bicyclic systems could form, but the “or” part would mean that the ring is formed from R10, R11 and the heteroatom of the ring – not any carbon of the ring. But there are two variables here, R10 and R11, and they

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cannot both attach to the heteroatom N because the N has only one H to replace (R60=H). To form the ring, one must use either one or two carbons, or use one carbon and a heteroatom, but it cannot be done with heteroatom alone. If applicants disagree, they are invited to draw such a ring.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-12, 22-23, 27-29, 41-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-11 of U.S. Patent

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No. 6821978. Although the conflicting claims are not identical, they are not patentably distinct from each other because of overlap.

The claims in this case are drawn to R4 as optionally substituted heterocycloalkyl, e.g. tetrahydropyranyl as see in e.g. claim 42. However, the parent case also has tetrahydropyranyl in its claims 10-11. It is not at all clear why that material is present in the patent.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

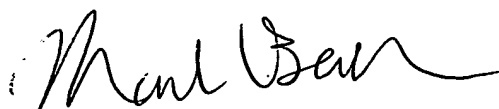
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Berch
Primary Examiner
Art Unit 1624

9/28/05